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# The Department of Defense Pharmacoeconomic Center

PEC UPDATE
October 2002, Vol. 03, Issue 1, www.pec.ha.osd.m

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# In This Issue . . .



## A web forum for DoD **Health Care**

**RxNet** 

We are pleased to announce the launch of RxNet, an internet-based web forum (aka a web bulletin board) for health care professionals caring for DoD beneficiaries. RxNet features include e-mail digests, thread watching, attachments, and the ability to host a wide variety of public and private forums. Get in on the ground level visit www.dodrxnet.org today!



## Editorial: Invest in RxNet: A Good **Return on Time & Effort**

CAPT Joe Torkildson on why RxNet will perform better than the stock market.



# **Epidemiology: What's Pharmacy Got** to Do with It?

CDR Denise Graham kicks off an "every other issue" series on pharmacoepidemiology & outcomes research. Look for more articles on study design, evidence based medicine, statistics (eek!), and practical examples.



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**Editorial: Why Evidence Based** Medicine? DoD P&T Committee **Highlights** Summary of Changes to the **BCF & NMOP Formulary** Barb's Barbs: **Evidence Based Medicine Links Generic Metformin New Drug Watch** PDTS Corner: Update on the **Pharmacy Data** Transaction Service

# **Coming Up**

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# Barb's Barbs: Drugs for Donuts?



You're just going to have to read this one.



# **2003 DoD Pharmacoeconomics & Pharmacy Benefit Conference**

The 2003 DoD Pharmacoeconomics & Pharmacy Benefits Conference will be held January 12 - 15, 2003, at the St. Anthony Hotel in San Antonio, Texas. The theme is "Measuring the Clinical Outcomes of Drug Therapy."



## **New Drug Watch**

A little bit of this, a little bit of that.



#### **PDTS Corner**

**Update on the Pharmacy Data Transaction Service** 

A Short Note About Data Integrity - Hector Morales, PDTS Customer Service Center Help Desk Manager, offers congratulations to everyone on database cleanup. But—keep an eye on your antidiabetic agents...

**Data Integrity Alerts -** Things to watch out for: using the correct NDCs for fluoxetine, simvastatin (Zocor), conjugated estrogens/medroxyprogesterone (Prempro), & Precision QID blood glucose test strips; multiple NDCs (for compounding use only!)

Top 10 Level 1 Drug-Drug Interactions for August 2002 by Point of Service



# Excellent Quote of the Month

"But innovators have to be willing to take a chance and invest their time first, with nothing more than the belief that they will get something of value in return."

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# PEC Update Information

### Subscribing

Would you like to receive the e-mail newsletter direct to your Inbox? Let us know by e-mailing Carol Scott, the PEC secretary, at carol.scott@amedd.army.mil.

#### **Editors' E-mails**

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### Submitting Articles

Do you have an article you'd like to see published in the *PEC Update?* Just send CAPT Torkildson or Shana Trice an e-mail, or call the PEC at DSN 421-1271,

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# Publication Schedule

The PEC Update is published 10 times per year (monthly except July and December. On the grounds that no one is paying much attention those months, anyway...).

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Dave Bretzke
Clinical Pharmacist
DoD Pharmacoeconomic Center

The Military Health System offers little in the way of collaborative environments. We at the PEC feel that this is detrimental to those involved in the delivery of medical care, particularly with drug therapy. The proper utilization of medications greatly affects the clinical, economic, and humanistic outcomes of patient care and, as this is our mission, we continue to identify new opportunities to improve communication with those involved in the provision of drug therapy throughout the Military Health System. Greater communication on key pharmacy benefit issues, such as formulary management, pharmaceutical contracting and clinical practice guideline development, leads to better decisions and delivery of a more consistent pharmacy benefit. To accomplish this, the PEC has established a web forum called RxNET, which can be found at www.dodrxnet.org.

#### **RXNET**

RxNET is an internet-based web forum (also known as a web bulletin board) for health care professionals caring for DoD beneficiaries. Hopefully, RxNet will improve our ability to communicate with healthcare professionals while simultaneously providing a mechanism for healthcare professionals to communicate with one another. Our goals include:

- Maximize participation in the DoD P&T decision-making process
- Optimize the process of refining the Basic Core Formulary
- Increase field input on potential DoD-wide procurement strategies

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Enhance education in selecting cost-effective drug therapy

We hope that with the utilization of RxNET, the DoD medical and pharmacy communities gain much more than the PEC's goals. We hope that RxNET will provide users with an environment that fosters education and communication, allowing greater inter-service communication and increased collaborative efforts. RxNET should also be a great resource for healthcare providers new to the DoD. RxNET is a place to ask questions and share answers to the multitude of problems that we all encounter day-to-day. After all, why reinvent the wheel?

## Registration

RxNET is a restricted website. The intended audience is pharmacists, pharmacy techs, physicians, physician assistants, nurse practitioners, and other healthcare professionals providing care to DoD beneficiaries. If you are included in the above, go to RxNET and request a new user account. Please register with your .mil e-mail address if you have one; this makes the verification process automatic for us and therefore faster for you. Upon submitting a new user request, an e-mail will be sent to you. Please click (or paste) the link provided in the e-mail to verify your e-mail address. If you registered with a .mil address, your account should then be activated to enter RxNET. If you do not use your .mil address, your account will require authentication of your relationship to DoD healthcare. Once we have confirmed this, you will receive an e-mail accepting your account request.

## FAQs and the rules of engagement...

We have put together a Frequently Asked Questions (FAQs) page and an Etiquette page to assist users with common questions and rules of participation in RxNET. Links to each of these pages can be found at RxNET's pre-login front page (www.dodrxnet.org). Please review each of these pages prior to participating in RxNET. These guidelines were set up to ensure as much as possible that all discussions on RxNET will be professional and respectful. We hope and expect that this will be a place where people can opine on some "hot" issues. We know that people will disagree with one another; we expect that they will do so without getting personal. Our staff will do its part to ensure that this happens by pointing out to people when their behavior is inappropriate, and by preventing them from participating if the behavior continues. We won't censor content, but we will maintain civility.

### Once inside...

Once you have successfully navigated the registration process and login for the first time, you will be brought to main index page, showing you a buffet of available forum categories, forum topics and forum activity. Across the top of every page is the site menu. You can return to this index page with MAIN INDEX, you can change your personal information or settings in EDIT PROFILE, read or send private messages to other RxNET users in MESSAGES, search for information in SEARCH, look who's currently looking around too by clicking WHO'S ONLINE, and return to RxNET's pre-login front page (leaving the forum area) with EXIT.

#### View or add content

From the main site page, click the desired forum name to view the current posts. You may reply to existing posts, or begin a new one.

To ask a new question or begin a new thought or comment, click the **NEW POST** button after selecting the desired forum. You can start a new poll or survey, by clicking the **NEW POLL** button from here as well. Polls are essentially multiple-choice questions that any user can begin. Users can give comments to the question by **REPLY**ing to the poll after you vote.

#### **E-mail Notifications**

You may receive e-mail notification of new content in a few different ways:

- 1. You may 'subscribe' to a forum and receive an e-mail per forum subscription with the previous days posts (new discussions and replies). You can manage your subscriptions from **EDIT PROFILE** à Subscriptions.
- 2. You may watch a discussion (called a thread) and receive an e-mail for each addition (reply) to that particular thread. When viewing a post, click the **WATCH THREAD** button to activate. To stop watching a thread, go to **EDIT PROFILE**, then to **WATCHED THREADS**.
- 3. By default, when you post to a forum, direct replies to your post will generate an email notification to you. If you do not care to be notified about replies to your post, remove the appropriate check before posting to the forum.

#### **Attachments**

You can attach files to posts (new or replies) or private, user-to-user messages. If you just want to make a file available, please attach the file and post to the File Library forum. If the attachment is more pertinent to a particular discussion, feel free to post it there. There is a 5MB limit for each attachment and a limit of 2 attachments to private messages (no limit on forum posts).

## New forums/private forums

RxNET has the capability to add additional public or private forums. If you are interested in hosting a forum on a particular topic or would like a private forum for a specific audience, please click the **REQUEST NEW FORUM** link at the bottom of each page or go to the Support forum (off the main index page) and drop us a note.

## Go forth and do good things...

We hope that RxNET is will provide you with the information you desire, although there is no magical computer program that provides these answers. The information you receive is from other busy RxNET users just like you. Ultimately, the success or failure of RxNET solely relies on your willingness to contribute to the process, by giving your assistance when asked and engaging in conversations with others around you. We need four things from you to make this project successful:

- 1. Register.
- 2. Visit.
- 3. Use the information provided to make better decisions.
- 4. Take the time to let us know if you see a way that we can make it better.

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**EDITORIAL** 

# Invest in RxNet: A Good Return on Time & Effort



CAPT Joe Torkildson, MC, USN Director, Clinical Operations Division DoD Pharmacoeconomic Center

# **Editors' Letters**

Please send your letters to the editors to Dr. Torkildson at Joseph.Torkildson@amedd.army.mil

There have been lots of opinions expressed recently in many venues

decrying the information glut and communication overload being experienced by health care providers. New medical journals appear on almost a daily basis. Almost every week someone is mailing me an opportunity to pay them to read, digest, and spit out in abridged form all this information that I think I need to read to keep up. The irony is, at the same time more and more people seem to be complaining that it's getting harder and harder to get someone to listen to them, and to provide them an answer when they have a question. You search for an answer on the Internet and your search engine returns 1,500 hits, with no hint as to which site might be the best place to go for an answer. Some links are dead ends, some present incorrect or inaccurate information, and some are run by crackpots. Unfortunately, none come with a label that states, "We certify that 50% of the information contained on this site is wrong", or "Danger, this site is run by a nut." We hunger for a site that we can go to, ask a question, and get an answer that will help us do our job. Does such a site exist? Where can we find it?

Starting on 15 October, you can find it at <u>www.dodrxnet.org</u>. This will bring you to RxNET, a web forum developed for the express purpose of providing people involved in caring for DoD beneficiaries a place to openly discuss issues and find answers to questions regarding quality pharmaceutical care. The brainchild of Dave Bretzke, a civilian

#### **PDTS Corner**

Update on the Pharmacy Data Transaction Service Page 8 pharmacist who came to the PEC last year from a stint at Landstuhl, RxNET was created to fill the information gaps that Dave perceived to exist when he was in the field.

RxNet is designed to serve many functions:

- 1. It provides an opportunity for healthcare professionals to discuss medical issues that impact on the quality of care of their patients.
- 2. It provides subscribers a central location to reach resources within DoD to find answers to questions or publicize problems. For example, a Procurement forum has been established that will allow people to get answers to contracting questions, or let someone at DSCP know that they're having problems obtaining a contracted drug.
- 3. It provides subscribers an opportunity to weigh in with their opinions on questions regarding the clinical impact of upcoming formulary decisions. This will be the most efficient way for both providers and pharmacists to ensure that their voice is heard and their vote is counted when these questions are put to the field for input.
- 4. It provides groups within DoD healthcare to establish their own forums to further communication within their group. These can either be public, so anyone can read the messages posted to them, or private, where the messages are available only to those individuals admitted to the forum. We anticipate a small number of private forums; the whole purpose of RxNET is to further open communication, so we would prefer to minimize the splintering that can occur if a large number of groups segregate their messaging from the rest of the community.
- 5. It provides subscribers with a tremendous amount of flexibility when deciding how to use the site. Some subscribers want to be able to go every day or even keep the site open on their desktop so they can see what's going on all the time. As long as their computer is secure, that's fine. Some people want to be notified every time a response is posted to one of their messages. The system can do that. Some people want to receive only a digest of the messages that have been posted to a few of the forums they are interested in. They can set their profiles to do that, too. Dave recognized the many possible levels of interaction that people might want, and selected a software solution that provided maximum flexibility in meeting those needs and desires.

The bottom line is, we have a great product, backed by a knowledgeable and dedicated staff of pharmacists and physicians, which fills a huge need that exists in DoD healthcare. So how could it not be successful? Three words: Lack of buy-in. There are too many of us with too many years of

experience living the motto: "Harder than it has to be!" We can't bring ourselves to believe that someone in the government is actually going to put something together for the sole purpose of making our job easier. So we won't show up. Or we'll come and find something to complain about, but instead of complaining we'll just go away and not come back. And maybe then we'll tell ten of our friends not to bother going and checking it out either. If that happens, it will be killed by the same malady that killed dozens of other forums that I visited when we were evaluating different software packages and forum designs over the past several months: lack of traffic. If someone posts a question on Monday and has received no input by Thursday, they're not coming back. I saw sites in August where people posted a question in February, and they still had no responses. That's a dead forum!

I truly believe that this could be one of the best things that ever happened to DoD healthcare, but it's not free. We're not looking for your cash, we're looking for you to invest a little of your time, knowledge and expertise. Become a member; it's easy, and Dave's article elsewhere in the Update tells you how to do it. Subscribe to some forums if you don't plan on visiting every day, so you get a heads up when you might have an opportunity to provide some input. Monitor some keywords; if you're interested in knowing right away when someone posts something to a forum dealing with 'statins' or 'BCF' or 'kids', drop those words in a keyword search and receive an email when messages are posted about those topics. Think of RxNET as a source of answers to questions, and take the time to post a question there when you're in need of some assistance. When questions come up that you are knowledgeable about, take the time to post an answer: what goes around, comes around.

And a special plea to my fellow physicians: don't dismiss this as being for pharmacists only, or as not being worth your time. The first statement is simply not true. We have made a special effort to ensure that RxNET is as relevant to the people writing the prescriptions as it is to those who are filling them. The veracity of the second statement really depends on you. This is a sort of co-op: the degree of value that you perceive depends on how much others are willing to contribute, and vice versa. But innovators have to be willing to take a chance and invest their time first, with nothing more than the belief that they will get something of value in return. Please join me in doing that; I believe it will be worth it if you do.

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# **Epidemiology**What's Pharmacy Got to Do With It?

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CDR Denise M. Graham, MSC, USN Navy Pharmacy Officer DoD Pharmacoeconomic Center

#### Be careful what you ask for

A year ago I completed a masters degree in public health with a major in epidemiology, in which I learned more about how much I really don't know. I wanted to share some of the key things I learned in my program, so I asked to write a bimonthly article in the *PEC Update*. "Ask and you shall receive – now produce" said the editors. Unlike CAPT Torkildson's writer's block, which lasted 2 weeks, mine can last for months or even years. Thus I have recruited the help of colleagues: LTC Dave Bennett, who recently walked into the PEC with his PhD in pharmacy practice with a major in outcomes research and a minor in epidemiology; and LCDR Frank Williams, who obtained his Master of Science in epidemiology (concentrating in pharmacoepidemiology and infectious disease epidemiology) from Harvard at the same time I received my degree at Eastern Virginia Medical Center.

## **Epidemiology = Epidermis?**

I can't tell you how many people asked me, while I was still in my masters program, why I was studying diseases of the skin. Once I told them to relate it to the word "epidemic" it became much easier to explain.

The definition provided by John M. Last states that epidemiology is

"the study of the distribution and determinants of health-related states or events in specified populations and the application of this study to control health problems.

Study includes surveillance, observation, hypothesis testing, analytic research, and experiments.

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Update on the Pharmacy Data Transaction Service Page 8 **Distribution** refers to analysis by time, place, and classes of persons affected.

**Determinants** are all the physical, biological, social, cultural, and behavioral factors that influence health.

**Health-related states** and **events** include diseases, causes of death, behavior such as use of tobacco, reactions to preventive regimens, and provisions and use of health services.

**Specified populations** are those with identifiable characteristics such as precisely defined numbers.

Application to **control**...makes explicit the aim of epidemiology – to promote, protect, and restore health."<sup>1</sup>

#### How does epidemiology relate to pharmacy?

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The number of times I've been asked this question is, I suppose, a hidden driver of my desire to write this column. If you take out parts of the definition of epidemiology you can easily place the use of medications in the application to **control health problems** since many medications are used in primary and secondary disease prevention. Medications and vaccines are among the **determinants** of health related states.

From a public health perspective, **pharmacoepidemiology** can be utilized to assess the impact that vaccines and drugs have on the overall patterns of morbidity and mortality in well-defined populations. **Pharmacoepidemiology** is defined by John M. Last\* as:

"the study of the distribution and determinants of the **drug related events** in populations and the application of this study to efficacious drug treatment." <sup>1</sup>

**Drug related events** can be either beneficial and/or adverse. Therefore the aim is to describe, explain, and predict the uses and effects of drug treatment in a defined time, place and population. Pharmacoepidemiology can apply epidemiologic reasoning, methods, and knowledge in order to expand the health benefits of drugs and reduce their risks.

Hopefully this has provided some clarification of how pharmacy relates to epidemiology. Future column publications will include (but aren't limited to):

- A practical explanation of different study designs
- Pros and cons of different study designs

The role of epidemiologic studies in evidence based medicine

- Mathematical terminology used in epidemiology
- Statistical measures for each type of study design
- Practical examples from the field

We are open to suggestions for future articles—let us know what epidemiology and outcomes research topics you would like to learn more about. We'll then flip a coin & decide if we'll will entertain the suggestion and/or which one of us will write the article.

Denise M. Graham, Pharm.D., MPH Navy Pharmacy Officer DoD Pharmacoeconomic Center 210-295-2791 or 210-295-1271, DSN 421-Denise.Graham@amedd.army.mil



\*John M. Last, ed. A Dictionary of Epidemiology, 3rd Edition. New York: Oxford University Press; 1995.

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# **Barb's Barbs**



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**Drugs for Donuts?** 

### LtCol Barbara Roach, USAF, MC Air Force Medical Officer, DoD Pharmacoeconomic Center

We've all heard and probably said the same statements.



- "One pen or donut is not going to influence me to write for Gorillacillin<sup>TM</sup>".
- "I'm not influenced by anyone. I don't even know what company makes which drug."
- "Who's feeding us during checkout rounds today?"

And so on. Coming to the forefront again is the relationship between medicine, docs, pharmacists and the drug companies. The New York Times ran a story on 1 October about a draft policy that is in the public comment period currently and has been written by the Department of Health and Human Services. Is this a real problem? Are providers just a bunch of drug company junkies? Are the pharmaceutical reps all just a bunch of sleezeballs? Will Bonnie get through to Simon and Henry on As the World Turns<sup>TM</sup>? Has any of this been looked at scientifically? How did we get into this mess in the first place? Let's see if we can sort any of this out. [Here's where you can find the HHS draft policy: http://oig.hhs.gov/authorities/frnotices.html, if you care to read the 44 pages it emcompasses.] As this is the first of a two part series (just like the local new investigative team reporter, huh?), I'll do the easy part first.

I thought I'd look at all my own past sins first. I'm not going to tell you how long ago these occurred or you'd be able to guess that I wouldn't qualify for Retin- $A^{TM}$  from the mail order pharmacy. I never went to USUHS. They were too darned slow – I'd already bought my books for KU by the time they called to tell me I had an interview. I laughed, said "See

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ya" and hung up the phone. Guess they're having the laughs now. Anyway, due to my all-civilian, all on my own, "just paid off the loans finally last year" medical education (whew), I think I had a bit more exposure to some of the pharmaceutical companies than we typically see in the MTFs. Here are some I can remember:

- The \$100 or so honorarium you get for going to an hour long meeting and sharing your experience with a drug is a common "opportunity." I went to one of those when I was on my endocrine rotation. The drug we were discussing was this new hormonal patch that was much more convenient than taking a pill per the drug company's brochures. The endo fellow that conned me into going never showed up, so I had to discuss our experience with the drug. The conversation went sort of like this:
  - Pharmaceutical Rep: "Dr. Roach, tell us how the type of patients you're using our drug with and what problems or successes you've had so far."
  - Me: "I don't really think you want to hear the answer to that question. Do you have an alternate question I could answer?"
  - o **Pharm Rep:** "Well, we'd really be very interested in your comments. Please share them."
  - Me: "Well, there's a big problem with these things just falling off. The patient sometimes comes in wearing several of them at once in hopes that one will last out the entire day."
  - **Pharm Rep:** "Is the patient taking the backing off? None of the women complained of that sort of problem in our trials."
  - Me: "Well, the patient isn't exactly a woman at least not yet. But he (she?) wants to be. It's just that he's so hairy that his face gets a 5 o'clock shadow by noon and his chest..."
  - Pharm Rep: "I think we have all the information we need. Let's see how the next physician's patients have fared."

They never invited me back to another one of those kinds of meetings. I'm not sure why.

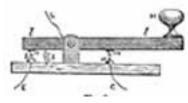
- I've had multiple in-hospital morning report breakfasts, lunch lectures, and checkout rounds meals. One of the dinners at checkout rounds was especially memorable as this drug rep always personally cooked the meals for us. He'd barbequed for this particular time and brought along this great tasting drink he'd made too. We finished our checkouts and listened to his talk about his product while we ate. Someone asked for his barbeque sauce recipe and someone else asked which type of powdered drink mix he used. He was happy to give out the sauce recipe and thrilled when someone commented on how good the drink was since he felt it proved his point that you couldn't taste that gritty powder he'd added to it (the drug he was giving us a pitch about). He just knew that side effect was imagined by most folks.
- A Krispy Kreme<sup>TM</sup> just opened this week in San Antonio but I haven't seen the donuts yet at Lackland. It's probably because the reps are still waiting in line to be served.



- Sometimes you get freebie samples in the civilian world of their product for your own use. I remember having a bad sinus infection that was grossing most everyone out. The rep said, "Here, try these. They'll work wonders for you." It was a bottle of sulfamethoxazole not a bottle with the week's supply you'd give a patient. No, this was the bottle you'd give to the pharmacy to count out the week's worth of pills for a whole bunch of patients. Like a twit, I took some. The next morning when I walked in to see my first patient she pulled back in horror and asked if I was infectious. Since I left so early to get to work that I pretty much just dressed in the dark, I hadn't looked at myself yet. So, I found a mirror. Best drug eruption I've seen to date. Every damn med student in the facility came by to look.
- My favorite toy was this little brain encased in plastic with a single neuron that had a magnet in it. You were supposed to work the neuron through the maze using the wand with magnet underneath – Ooops. That was from a Wendy's Kidspak Meal<sup>TM</sup>. Sorry.
- Here's a digital picture of what adorns my little cubicle. What does your office space look like? Baycol<sup>TM</sup> picture frame with your diploma in it? Lipitor<sup>TM</sup> mug for your coffee? Little stuffed Rhinocort<sup>TM</sup> nose? Squeezy Prozac<sup>TM</sup> pill or my personal favorite, the prostate-shaped Proscar<sup>TM</sup> soaps?
- Sometimes the company wants to pay for you to attend a lecture in a city other than the one you're located in. Some of these are very good talks and others aren't, just like Grand Rounds (I still fall immediately asleep remembering the horror of the Polar T3 syndrome talk one of our endo docs scheduled for Wilford Hall). I did accept one of these trips via the gift procedure for a day of lipid lectures in Chicago when I was Director of the Wellness Clinic (a large lipid clinic) at Wilford Hall. The rep had asked me to go several years in a row, but I always had something previously scheduled the week it always occurred. I had something that year too, but they let me send my NCOIC (an LVN equivalent) instead, since he saw many of the patients. He learned a lot and made use of the information he got.
- The same company tried to assist us at the Wellness Clinic by giving us some software they were developing to track patient outcomes. Wow. Something truly useful. I had to send them to Cardiology with the software program, since all we had were dumb terminals at Wellness and no one would give up even one lousy real computer for us to put the software in.
- The first pharmaceutical company presentation at the PEC that I attended nearly made then-CDR Brouker pass out when I whipped out a notepad to write on that had the logo of a competing company emblazoned on it.
- The last after work dinner talk I went to was an informal presentation at Borders<sup>TM</sup> when we first started working on a BCF issue and I wanted some more information in a setting outside of the PEC. I declined the \$5.00 Borders<sup>TM</sup> gift certificates they were giving out, but it amazed me to see some docs in Armani<sup>TM</sup> suits going up and asking for 10 or 20 of the gift certificates.

• I grab that little Sanford<sup>TM</sup> book whenever I see it, but it's been a long time now.

So is there anything wrong about accepting gifts from a pharmaceutical company? Does it really affect your ability to prescribe independently? We'll look at the evidence next month and evaluate the HHS draft (which suggests voluntary compliance). I'll leave you with these thoughts in the meantime:



• When I was enlisted and copied Morse Code, no one ever offered us any freebies (like that was a full, satisfying and useful job that there'd be any freebies to offer in the first place. Di-dah, di-dah, and di-dah. You'll know what that is

if you're a ditty-bopper.)

- When I got lucky enough to cross train out of Morse Code and work in the gym, no one gave me any free tennis shoes or baseball caps or anything.
- If you're going to accept something, consider Barb's all-guiding principle questions to ask yourself first. They are:
  - 1. Would I go to the lecture if it was just presented in my MTF instead of at a restaraunt?
  - 2. Would I mind being at the lecture if I knew that 60 Minutes<sup>™</sup> or the local news would be there and have my picture on the TV?
  - 3. Would my patients think it's ethical for me to accept a \$100 a plate meal when they are never offered such goodies?

Let me know what you think. You know I don't really care, but it will make you feel so much better. Whining is therapeutic. I do it often. Follow up next month for Part 2.



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# 2003 DoD Pharmacoeconomics & Pharmacy Benefit Conference

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The 2003 DoD Pharmacoeconomics & Pharmacy Benefit Conference will be held January 12 - 15, 2003, at the St. Anthony Hotel in San Antonio, Texas. The theme for the 2003 conference, which is sponsored by the University of Texas, is "Measuring the Clinical Outcomes of Drug Therapy." The conference is recommended for physicians, pharmacists, and nurses interested in measuring and improving clinical outcomes of drug therapy. Speakers from DoD and the VA will discuss the concepts of outcomes measurement with emphasis on the practical application of these concepts to MTF situations.

The agenda and registration forms for the conference are in preparation; they will be sent to individual MTFs and will be available on the PEC website in the near future. Questions may be directed to **COL Doreen Lounsbery** or **Dr. Eugene Moore** at the DoD Pharmacoeconomic Center, 210-295-1271 (DSN prefix 421-).

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# **New Drug Watch**



# Angela Allerman Clinical Pharmacy Specialist DoD Pharmacoeconomic Center

A short column this month, but a lot of variety.

## **Newly Approved Drugs From Head to Toe**

Some of these newly FDA-approved drugs may not be available until later this year, or in 2003.

#### **Dermatology**

### **Quick Links**

- Newly Approved
   Drugs from Head to
  Toe
- New Indications
- Labeling Changes
- New Precautions
- Did you know...
- Market Reintroduction
- Discontinuations
- New Guidelines

Clindamycin 1% / benzoyl peroxide 5% topical gel (Duac; Stiefel Laboratories) is indicated for topical use of inflammatory acne vulgaris. Store under refrigeration.

**Tazarotene topical cream (Avage, Allergan)** received approval for the mitigation of facial wrinkles on 30 Sep 02. The same active ingredient is also available under the trade name Tazorac for treating psoriasis and acne.

### **Neurology / Psychiatry**

Buprenorphine/naloxone (Suboxone) and buprenorphine (Subutex; Reckitt Benckiser/Schering) sublingual tablets are now approved for the treatment of opiate dependence. Physicians must meet certain criteria before they can be certified

#### **PDTS Corner**

Update on the Pharmacy Data Transaction Service Page 8 to use the two drugs. In contrast to methadone maintenance treatment programs, patients can be supervised and treated in the physician's office. Pharmacists will need to verify physician credentials by calling **1-866-BUP-CSAT** before Suboxone and Subutex can be dispensed to the patient. For additional information, visit <a href="www.suboxone.com">www.suboxone.com</a>. These drugs are Schedule III.

#### Immunology / Oncology

Adefovir dipivoxil tablets (Hepsera, Gilead) is a nucleotide antiviral analog approved for treatment of chronic hepatitis B in patients with active disease. This product is likely to be promoted for patients resistant to lamivudine (Epivir-HBV; GlaxoSmithKline).

**Oxaliplatin injection (Eloxatin; Sanofi)** is indicated for use in combination with 5-flurouracil/leucovorin in patients with metastatic colon/rectal CA whose disease has recurred or progressed despite treatment with 5-FU and irinotecan.

Rasburicase (Elitek; Sanofi) is approved for managing elevated plasma uric acid levels in pediatric patients with leukemia, lymphomas, and solid tumor malignancies who are receiving chemotherapy treatment expected to cause tumor lysis. It is administered as an IV infusion over 30 minutes. This biologic agent is a recombinant urate-oxidase enzyme.

#### **Endocrinology**

**Rosiglitazone / metformin combination tablets** (Avandamet; GlaxoSmithKline) are indicated for use in type 2 diabetics as an adjunct to diet and exercise in patients already taking the two tablets separately, or who are not adequately controlled on metformin alone. The tablets are available in three strengths: 1 mg/500 mg; 2 mg/500mg and 4 mg/500 mg.

#### Cardiology

**Eplerenone (Inspra, Pharmacia)** is an aldosterone antagonist approved on 27 Sept 02 for hypertension. Eplerenone may be associated with a lower incidence of gynecomastia than spironolactone. As expected, hyperkalemia was reported in

clinical trials. This drug is not expected to launch until 2003, likely after the Pharmacia/Pfizer merger.

#### Gastroenterology

Alosetron (Lotronex; GlaxoSmithKline) will be re-entering the market for the treatment of diarrhea-predominant irritable syndrome in women who have failed to respond to conventional therapy. A prescriber program and informed consent will be required. Availability is expected in early Nov 02. Alosetron was withdrawn from the market in 2000 due to GI adverse effects.

**Tegaserod (Zelnorm; Novartis)** was approved on 24 Jul 02 for the short term treatment of constipation-predominant irritable bowel syndrome in women. Tegaserod is a 5-HT4 receptor partial agonist.

#### **Infectious Disease**

Amoxicillin/clavulanate potassium (Augmentin XR; GlaxoSmithKline) has 62.5 mg of clavulanate, instead of the 125 mg found in other Augmentin formulations. It is approved for treating sinusitis or community acquired pneumonia caused by *S. pneumoniae* or other beta-lactamase-producing bacteria that have reduced susceptibility to penicillin. Don't confuse this product with Augmentin ES, the pediatric formulation which came out last year.

### **Urology**

**Dutasteride (Avodart; GlaxoSmithKline)** is a "second generation" 5-alpha reductase inhibitor approved for treating symptomatic benign prostatic hyperplasia (BPH) in men with an enlarged prostate. Dutasteride is labeled to improve symptoms, reduce the risk of urinary retention, and reduce the risk of surgery. It inhibits both the type 1 and type 2 enzymes responsible for conversion of testosterone to dihydrotesterone. Finasteride (Proscar, Merck) has similar indications.

#### Women's Health

Ethinyl estradiol 25 mcg / norgestimate (varying doses

(OrthoTri-cylen Lo; Ortho) is a new triphasic oral contraceptive agent with a low-dose estrogen component. It contains 25 mcg of ethinyl estradiol, compared with the 35 mcg found in the original Ortho Tri-Cyclen formulation.

#### **New Indications**

- Angiotensin II receptor blockers (ARBs) are in the news again this month (see last month's column for a discussion of valsartan for CHF). Irbesartan (Avapro, Bristol-Myers Squibb) and Iosartan (Cozaar; Merck) are now both indicated for treating diabetic nephropathy (elevated serum creatinine and proteinuria) in patients with type 2 diabetes and hypertension. New: A "Place in Therapy" guide concerning the recommended uses of ARBs is now available on the new RxNet web forum (sign up at www.dodrxnet.org).
- **Glyburide / metformin** tablets (Glucovance; Bristol-Myers Squibb) are now approved for use in combination with thiazolidinediones (rosiglitazone, pioglitazone) when adequate glycemic control is not achieved.
- Valacyclovir (Valtrex; GlaxoSmithKline) is now approved for treating cold sores at a dose of 2 grams bid for one day. The convenience of a one-day treatment will be stressed in advertising.

#### **Labeling Changes**

• The package insert for **candesartan (Atacand; AstraZeneca)** now claims a 20% better pressure reduction compared to **losartan (Cozaar; Merck)**. A review of the data submitted to the FDA from two trials comparing starting doses of candesartan 16 mg with losartan 50 mg (n~1200) showed candesartan was more effective than losartan at reducing mean sitting diastolic blood pressure, although the magnitude of the difference was small (2 mmHg) and may not be considered clinically significant. The FDA considers a decrease of at least 3 mmHg to be a clinically meaningful reduction of diastolic blood pressure.

#### **New Precautions**

• Sildenafil (Viagra, Pfizer) has a new precaution recommending avoiding use of alpha blockers within 4 hours, if using a sildenafil dosage greater then 25 mg. The concurrent use of the two drugs has resulted in symptomatic hypotension. The new labeling comes from data from ongoing clinical trials.

#### Did you know...

You can access the FDA website link

www.fda.gov/medwatch/SAFETY/2002/safety02.htm for a listing of drug, biologic, or dietary supplement safety alerts. The most recent safety-related labeling changes for conjugated estrogens/ medroxyprogesterone acetate (Prempro/Premphase; Wyeth) and mefloquine (Lariam; Roche) can be found here.

#### **Market Re-introduction**

• **Urokinase (Abbokinase; Abbott)** has been re-introduced to the market, following suspension of production in 1999 due to manufacturing deficiencies. The product is now only indicated for pulmonary embolism, however, additional studies are underway to re-submit an indication for catheter clearance. Abbott does not plan to re-submit an application for coronary artery thrombosis.

#### **Discontinuations**

- Schering Plough's beclomethasone (Vancenase) nasal spray in 84 mcg and 42 mcg strengths has been completely discontinued, due to an agreement with the FDA over manufacturing issues. Other Schering-Plough products have also been discontinued (see <a href="https://www.fda.gov/cder/dmpg/SP\_consent\_decree.htm">www.fda.gov/cder/dmpg/SP\_consent\_decree.htm</a>).
- Danaparoid sodium injection (Orgaran; Organon) has been discontinued due to shortage of the active ingredient. Danaparoid was indicated for the prophylaxis of DVT/PE after hip replacement surgery, but was sometimes used offlabel for anticoagulation in patients with heparin-induced thrombocytopenia. Questions can be directed to Organon's Medical Services department at 1-800-631-1253.

#### **New Guidelines**

• Recommendations for treating head lice (Pediculosis capitis) have been released by the American Academy of Pediatrics. The drug of choice is permethrin 1%, due to low toxicity and decreased risk of allergic reaction. Another key aspect of the guideline is that parents are advised to send healthy children to school and not keep them at home during an outbreak. Another misconception is that lice hop or jump from person to person; this is a fallacy—they crawl. See <a href="http://www.aap.org/policy/0203.html">http://www.aap.org/policy/0203.html</a> or the September issue of Pediatrics (Frankowski BL, Weiner LB. Head lice. Pediatrics 2002;110 (3):638-43) for the recommendations.

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# **PDTS Corner**

**Update on the Pharmacy Data Transaction Service** 



#### **Quick Links**

A Short Note on Data Integrity

Data Integrity Alerts

Top 10 Level 1 Drug-Drug Interactions

for August 2002 by Point of Service

## A Short Note on Data Integrity

By Hector Morales, PDTS CSSC Help Desk Manager; ACS Task Lead

We at the Customer Service Support Center just wanted to thank you all for your prompt responses to our calls and e-mails regarding data integrity issues and for taking the time during your very busy days to work on them. We have noticed a decrease in the number of data integrity issues being reported from many sites. This decrease is a direct result of your attention, hard work, and ideas about improving the process.

Recently we realized issues with many of the antidiabetic agents. Take a good look at all of your antidiabetic agents to assure that you are using the correct NDC numbers and that providers and pharmacy users are selecting the correct product and quantity (depending on package size) for each prescription. When the wrong quantity is entered in CHCS it affects the day supply, metric quantity, and cost of that prescription recorded by PDTS. All three issues could influence decisions made using those data.

#### Remember

You should be using the NDC # of the product you are dispensing from the shelf.

## **Data Integrity Alerts**

By Crystal Little, CPhT, CHDM

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#### PDTS Project Officer, ACS

Items sent out to the field recently:

NDCs for Fluoxetine: Effective immediately, all sites should be using the following NDC#s for the contract generic for fluoxetine (Mallinckrodt). Please refer to the chart opposite to enter the correct NDC# by strength and bottle size dispensed at your site.

Multiple NDCs are for Compounding Use **ONLY:** The PDTS CSSC has discovered that many sites are entering multiple NDC#s under **SFM>FOM>ADN** for medications. I've attached a Word document that explains why this should not occur **UNLESS** it is for locally compounded medications **ONLY**. If a prescription is entered that has multiple NDC#s in the drug file for that medication, it comes to PDTS as a compounded item. We have seen the following examples come across marked as compounded medications: acetaminophen (Tylenol) #3, birth control. We have observed in our discussions with some sites that they are entering multiple NDC#s to save time when switching products, rather than the manufacturer or a generic vs brand. While they are all trying their very best to keep up with the mandatory cleanup, sites need to ensure that they only enter one NDC# per medication in the drug file **UNLESS** it is a locally compounded item.

# Contracted Product: Fluoxetine 10 mg, 20 mg caps Applicability: All DoD and

Applicability: All DoD and

DVA activities

Type of Award: Mandatory source procurement Effective Date: 10/Jun/02 -

09/Jun/03

Length of Contract: One year;

four option years

Manufacturer: Mallinckrodt,

Inc

Contract Number: V797P-

9060

Drug strength, package size	NDC #	Price
10mg 100's	00406- 0661-01	\$ 2.54
10mg 500's	00406- 0661-05	\$ 12.50
20mg 100's	00406- 0663-01	\$ 3.20
20mg 500's	00406- 0663-05	\$ 15.52

**NDCs for Simvastatin:** Effective immediately, those sites using NDC#s for Zocor that end in 61 (package size of 60 per bottle) need to correct their drug files. The bottles of 60 were discontinued by the manufacturer and are not included in the contract. Please refer to the chart opposite to enter the correct NDC# by strength and bottle size dispensed at your site. Continued use of the NDC#s ending in 61 will show prices of \$3.50 per tab in PDTS—this must be changed immediately! We appreciate your cooperation in this matter.

NDCs for Conjugated Estrogens/Medroxyprogesterone (Prempro): We were checking out the NDC#s for Prempro being used at the MTFs. Currently,

there is only one NDC# per strength that should be used for Prempro. In other words, in the drug file

(**SFM>FOM>ADN**), your site should have the following NDC# populated for Prempro:

Prempro 0.625/5mg 00046-0975-06

Prempro 0.625/2.5mg 00046-0875-06

Please ensure that your drug file is corrected.

#### **NDC for Precision QID Test Strips:**

The PDTS CSSC has discovered that many sites are entering 57599-7402-01 under **SFM>FOM>ADN** for Precision QID Test Strips. This NDC# is for the Precision QID Sensor, therefore PDTS shows that the sensor was sent; however, the quantity clearly shows it should have been for the strips. We are sending out results for the month of August 02 to the sites that are using the incorrect NDC# for test strips, but all sites should take a look at their test strips and ensure that they have the NDC# entered correctly according to the NDC# that is on the box of test strips. Sites should also edit the prescriptions once they have the correct NDC# entered.

# Top 10 Level 1 Drug-Drug Interactions by Point of Service

By COL (Ret) Roger Williams, PDTS CSSC Clinical Support Supervisor

The feature in PDTS that enhances patient safety is the process of conducting Prospective Drug Utilization Reviews (ProDURs). PDTS conducts on-line ProDURs (clinical screens) on all medications dispensed, regardless of the DoD point of service the patient used to have the prescription filled. Pharmacy personnel need to be

### Contracted Product: Simvastatin 5mg, 10mg, 20mg, 40mg, 80mg tablets

Applicability: Applies to all DoD

activities.

Type of Award: Mandatory source

procurement.

Effective Date: 01/Oct/99 - 19/Feb/03 Length of Contract: Eighteen month initial with 2-one year options (currently in

last option year)

Manufacturer: Merck & CO

**Contract Number:** SP0200-99-D-0505 **Note:** Note: 60 tablet pkg. sizes d/c'd by

mfg. eff. 9/5/01

1111g. 011. 07	0,01		
Drug strength, package size	NDC	Drug strength, package size	NDC •
5 mg 30's	00006- 0726-31	*20mg, 100's U/D	00006- 0740- 28
5mg, 90's	00006- 0726-54	*20mg, 1,000's	00006- 0740- 82
5mg, 100's U/D	00006- 0726-28	*20mg, 10,000's	00006- 0740- 87
5mg, 1,000's	00006- 0726-82	*40mg, 30's	00006- 0749- 31
10mg, 30's	00006- 0735-31	*40mg, 90's	00006- 0749- 54
10mg, 90's	00006- 0735-54	*40mg, 100's U/D	00006- 0749- 28
10mg, 100's U/D	00006- 0735-28	*40mg, 1,000's	00006- 0749- 82

aware that with the activation of PDTS, the number of clinical screenings could increase depending on how frequently patients use multiple prescription sources. PDTS clinical screens are performed only on those medications the patient obtains from outside of the dispensing site's host cluster. It will not duplicate clinical warnings generated from within the CHCS host system.

For further information about the PDTS DURs, see my article in the Mar 2002 PEC Update.

## Top 10 Potential Level 1 Drug-Drug Interactions in MTFs, August 2002

Rank	Medications involved	#
1	Ibuprofen / Ketorolac tromethamine	295
2	Ketorolac tromethamine / Naproxen	134
3	Nitroglycerin / Sildenafil citrate	84
4	Ketorolac tromethamine / Rofecoxib	73
5	Isotretinoin / Minocycline HCI	58
6	Celecoxib / Ketorolac tromethamine	53
7	Aspirin / Ketorolac tromethamine	32
8	Doxycycline hyclate/ Isotretinoin	31
9	Ketoconazole / Simvastatin	30
10	Ketorolac tromethamine/Indomethacin	24

Top 10 Potential Level 1 Drug-Drug Interactions in the Retail Network, August 2002

10mg, 1,000's	00006- 0735-82	*80mg, 30's	00006- 0543- 31
10mg, 10,000's	00006- 0735-87	*80mg, 90's	00006- 0543- 54
*20mg, 30's	00006- 0740-31	*80mg, 100's U/D	00006- 0543- 28
*20mg, 90's	00006- 0740-54	*80mg, 1,000's	00006- 0543- 82

Rank	Medications involved	#
1	Nitroglycerin / Sildenafil citrate	112
2	Ibuprofen / Ketorolac tromethamine	104
3	Ketorolac tromethamine / Naproxen	74
4	Ketorolac tromethamine / Rofecoxib	64
5	Celecoxib / Ketorolac tromethamine	62
6	Isotretinoin / Minocycline HCI	60
7	Ketoconazole / Simvastatin	42
8	Itraconazole / Simvastatin	39
9	Isotretinoin / Doxycycline Hyclate	34
10	Entacapone / Selegiline HCl	33

Top 10 Potential Level 1 Drug-Drug Interactions in the NMOP, August 2002		
Rank	Medications involved	#
1	Nitroglycerin / Sildenafil citrate	75
2	Ketoconazole / Simvastatin	13
3	Amiodarone HCI / Gatifloxacin	11
4	Celecoxib / Ketorolac tromethamine	8

5	Ketorolac tromethamine / Rofecoxib	7
6	Ketorolac tromethamine / Naproxen	6
7	Entacapone / Selegiline HCI	6
8	Intraconazole / Simvastatin	6
9	Gatifloxacin / Sotalol HCl	5
10	Amiodarone HCI / Moxifloxacin HCI	4

## **The PDTS Customer Service Support Center**

The PDTS CSSC strives to provide world-class customer support to all Military Health System users while enhancing the operational effectiveness and ensuring the quality of information maintained within the Pharmacy Data Transaction Service. The PDTS CSSC comprises the Pharmacy Benefit Operations Division of the PEC and is co-located with the Clinical Operations Division of the PEC at Ft. Sam Houston, TX.

The PDTS CSSC has an e-mail address for questions, comments, concerns, or report requests:

### PDTS@cen.amedd.army.mil

Drop us an e-mail! We will respond via e-mail or call you within 1 business day.

#### Or call the PDTS CSSC at:

- DSN: 471-8274
- Toll-free commercial:
   1-866-275-4732
   (1-866-ASK4PEC)
- Local commercial (San Antonio): (210) 221-8274
- OCONUS: (AT&T access code)+866-275-4732

#### **Need more information?**

Many materials pertaining to PDTS, including trouble call procedures, the PDTS Report Request Form, business rules, and interchange control documents (ICDs), are available in the PDTS section of the PEC website. Just go to

www.pec.ha.osd.mil/pdts/pdts\_documents.htm and browse through the options on the left-

hand navigation bar.

In addition, many articles on various aspects of PDTS and the PDTS CSSC have been published in recent issues of the *PEC Update*. Please visit the PEC Update page on the PEC website - www.pec.ha.osd.mil/ac03000.htm - for back issues.

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